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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,749	06/11/2001	Jacob Richter	2390/50002	2906

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EXAMINER	
PANTUCK, BRADFORD C	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/878,749	RICHTER, JACOB	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 11, 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *13-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a stent and balloon catheter, classified in class 623, subclass 1.11.

II. Claims 13-21, drawn to a method of implanting a stent, classified in class 623, subclass 1.11.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used for a different process such as expanding a stent without bursting the inner balloon.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with John Altmiller on December 22, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,419,685 B2 to DiCaprio. Regarding Claim 1, DiCaprio discloses a stent/balloon catheter combination, including all of the limitations set forth by Applicant. DiCaprio discloses a first balloon (116) having a wall thickness of 0.0002-0.0007 inches [Column 11, lines 24-27] overlayed by a second balloon (114) having a wall thickness of 0.0007-0.004 inches [Column 12, lines 4-6]. DiCaprio's stent may be shorter than inner balloon (116) [as shown in Fig. 12] or longer than the inner balloon (and shorter than outer balloon (114)) [as explained in Column 11, lines 9-11]. Because the outer balloon is thicker than the inner balloon, and because it is larger, it will have necessarily have greater burst strength. That is, it takes more pressure to burst a thicker/larger balloon than it will to burst a thinner/smaller balloon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 2-8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,419,685 B2 to DiCaprio et al. Although the specific burst pressures claimed by the applicant are not explicitly set forth by DiCaprio, it would have been an obvious matter of design choice to modify the respective balloons to have the claimed burst pressures, since applicant has not disclosed that the precise recited pressures provide any advantage, or solve a stated problem, or is used for any particular purpose. In other words, Examiner contends that the invention would *work equally well* if the respective burst pressures of the two balloons were 3 atmospheres and 6 atmospheres.

Alternatively, it is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to *prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.*

3. Regarding claims 7-10, inner balloon (116) may be formed of a compliant or non-compliant material [Column 11, lines 28-29]. Balloon (114) "may be any conventional balloon for catheter delivery" [column 11, lines 50-52], which includes both compliant and non-compliant materials.

4. Regarding Claim 11, guide wire (12) extends through the balloon catheter and extends out of the distal (central port), adjacent to the balloons [Fig. 5 for example].

5. Claims 1 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,358, 487 to Miller in view of U.S. Patent No. 6,419,685 B2 to DiCaprio et al. Miller discloses an inner balloon and an outer balloon, as set forth by Applicant. One knows that the burst strength of the outer balloon is greater than that of the inner balloon because Miller explains that the inner balloon will burst and the outer balloon will contain the pressure and will be capable of receiving even more pressure [Column 3 line 64 to Column 4 line 5; see Fig. 2]. Miller does not disclose using his balloon catheter to deliver a stent, but DiCaprio uses a very similar device to deliver a stent of the same proportions recited by Applicant. DiCaprio teaches that delivering a stent with a balloon catheter is well known in the art [Column 1, lines 37-42] and therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use Miller's balloon catheter to deliver a stent to an interior body lumen, as exemplified and taught by DiCaprio.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,342,305 to Shonk

U.S. Patent No. 4,744,366 to Jang

U.S. Patent No. 5,704,913 A to Abele et al.

U.S. Patent No. 6,136,011 to Stambaugh

U.S. Patent No. 6,605,056 B2 to Eidenschink et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP
January 3, 2005

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
1/7/05